

PSJ3

Exhibit 213D

## Supreme Court Case

- United States v. Moore  
423 U.S. 122 (1975)
  - Usual course of professional practice
    - Patient with a Medical Complaint
    - History
    - Physical Examination
    - Nexus Between Complaint/History/Exam and Drug Prescribed

## DEA Internet Policy

- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescriptions not issued in the usual course of professional practice are not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances



## VIPPS

- National Association of Boards of Pharmacy
  - Licensed, legitimate, Inspection
  - Verified Internet Pharmacy Practice Sites
  - 14 VIPPS Approved Pharmacies as of 06-27-2005
  - [www.nabp.net/vipps/consumer/faq.asp](http://www.nabp.net/vipps/consumer/faq.asp)

## American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
  - valid patient-physician relationship, includes, but not limited to:
    - History and physical exam
    - Dialogue with patient
    - Follow up to assess outcome
    - Maintain medical record
    - Include electronic prescription in patient's medical record



## Federation of State Medical Boards

- Created Model Guidelines for the Appropriate use of the Internet in Medical Purpose
  - Treatment and consultation made in an online setting will be held to same standard as face-to-face settings.
  - Treatment based solely on an online questionnaire is not acceptable

## Suspicious Orders

- 21 CFR 1301.74
- Requires that registrants design and operate a system to identify suspicious orders
- Report suspicious orders to DEA when discovered



## Suspicious Orders

- Reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

## Suspicious Orders

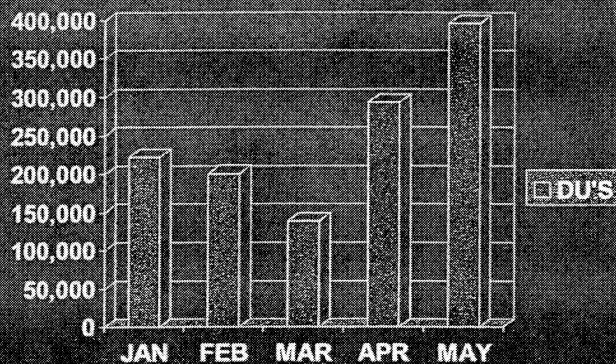
- DEA cannot tell a distributor if an order is legitimate or not
- Distributor must determine which orders are suspicious and make a sales decision



## Example #1

- Retail pharmacy
  - Quantities of drugs
  - Range of drugs sold – only Phentermine
  - % controlled and % non-controlled
  - Size of orders over time
  - Location of store

## Example #1



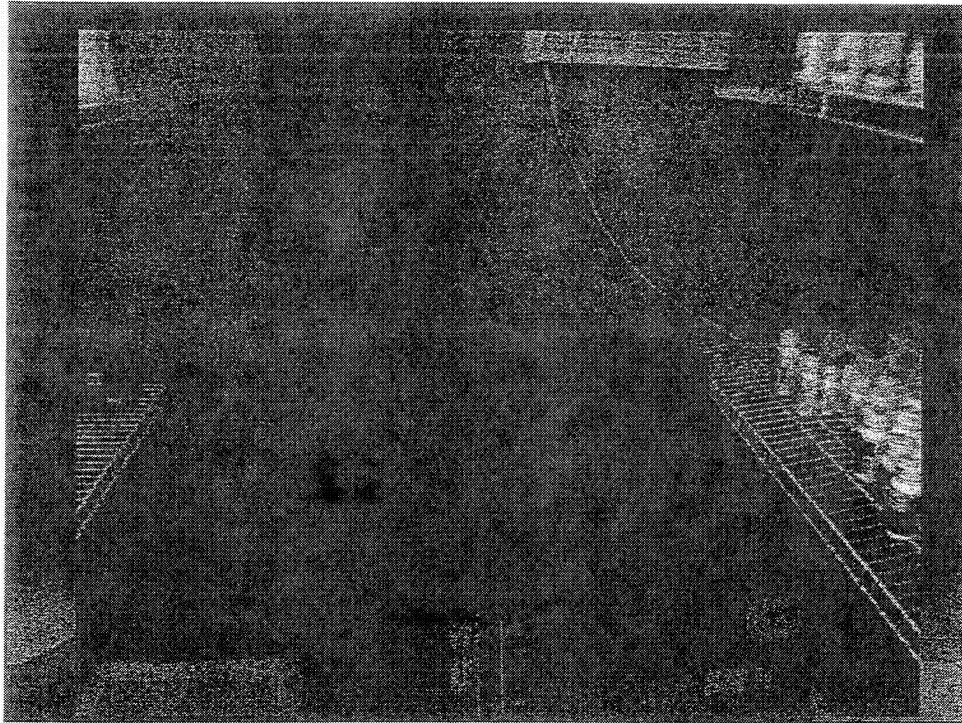


## Example #2

- Retail Pharmacy
  - Location of store
  - Only Hydrocodone and Alprazolam
  - Very large quantities
  - FedEx boxes for delivery

## ANOTHER PHARMACY





### Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit